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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WINKLER, ULRIKE	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/963,761	ARAZI ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 19-35* is/are pending in the application.

4a) Of the above claim(s) *5 and 23-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-15, 19-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I with further election of (1) ZYMV and (A) cMyc: SEQ ID NO 8-19 and 31 in Paper No. 15 is acknowledged. The traversal is on the ground(s) that the method of expressing a heterologous protein in a plant and a method of vaccinating will necessarily use the vector of Group I. This is not found persuasive because Inventions of Groups I, II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the vaccine can be made by producing the antigenic peptide synthetically which is a materially different process than using a plant virus to produce the antigenic peptide.

The requirement is still deemed proper and is therefore made FINAL.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Drawings

The drawings are objected to, please see Notice of Draftsperson's Review attached to the Election/Restriction requirement of Paper No. 9. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims in combination contain the limitation that "at least a portion of the heterologous peptide" when combined with the limitation of the prior claim "a heterologous nucleic acid" it is no clear how much nucleic acid sequence is required in order to meet the limitation of being at least a "at least a portion of the heterologous peptide". The meets and bounds of what is encompassed by the claim is not clear.

Claims 1, 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 contains the limitation that "modified by deletion of at least one amino acid residue". Deleting one amino acid residue is clear. What is not clear is how many more amino acids may be deleted and still maintain the character of being a potyvirus amino terminal domain. How much can be deleted from the amino terminus and still be within the meets and bounds of the claim.

Claims 1, 3 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 contains the limitation that "influences a biological activity", what biological activity is to be influenced? The virus or the plant? The meets and bounds of the limitation "influences a biological activity" in the claim is not clear

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6-13, 15 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Fernandez-Fernandez et al. (Federation of European Biochemical Societies, 1998).

The instant invention is drawn to a recombinant vector expressing a heterologous peptide at the amino terminus of a potyvirus coat protein. The vector comprises enough viral sequence to allow viral replication and spread within the plant. The heterologous sequence can be from a wild type potyvirus. The potyvirus of is a ZYMV. The virus can either be in the form of a DNA sequence, an RNA sequence or a cDNA sequence. The coat protein includes an amino terminal domain, wherein the modification is by deletion of "at least one amino acid residue". The vector can also have additional amino acid residues added to the polyprotein. The recombinant vector further comprises an amino acid substitution in the HC-Pro gene. Aphids do not transmit the virus effectively. The recombinant vector comprises a c-Myc tag.

Fernandez-Fernandez et al. disclose the construction of a recombinant potyvirus (plum pox potyvirus vector; PPV) which comprises a heterologous nucleic acid sequence encoding canine parvovirus VP2 capsid protein (CPV). The non-aphid transmissible PPV was used for the cloning of the 15 amino acid sequence of CPV (see material and methods) into the PPV vector. The mutant viruses created in the reference were able to infect plants and replicate (see page 230, column 2, last paragraph). The PPV amino terminal domain was deleted of at least 45 nt (15 amino acids) that were then replaced by the addition of 45nt from the CPV sequence in order to established the number of amino acids present in the wild type PPV (see page 231, column 1, 1st paragraph). Since the sequence does not contain additional amino acids the sequence would be expected to have an isolelectic point that is "similar" to the wild type PPV. Additionally, the chimeric PPV-CPV particles were tested in laboratory animals (rabbit and mouse) to see if they are able to induce neutralizing antibodies (see page 233, table 1 and page 234, table 2). Therefore, the instant invention is anticipated by Fernandez-Fernandez et al.

Claims 1, 2, 3, 6-9, 15 and 22 are rejected under 35 U.S.C. 102(a) as being anticipated by Verrelmann et al. (Journal of Virology, 2000).

The instant invention is drawn to a recombinant vector expressing a heterologous peptide at the amino terminus of a potyvirus coat protein. The vector comprises enough viral sequence to allow viral replication and spread within the plant. The heterologous sequence can be from a wild type potyvirus. The potyvirus of is a ZYMV. The virus can either be in the form of a DNA sequence, an RNA sequence or a cDNA sequence. The coat protein includes an amino terminal domain, wherein the modification is by deletion of "at least one amino acid residue". The vector

can also have additional amino acid residues added to the polyprotein. The recombinant vector further comprises an amino acid substitution in the HC-Pro gene. Aphids do not transmit the virus effectively. The recombinant vector comprises a c-Myc tag.

Verrelmann et al. disclose production of non-aphid transmissible PPV which has the coat protein replaced with the coat protein of a heterologous potyvirus (see figures 1 and 3). Since the sequence does not contain additional amino acids the sequence would be expected to have an isolelectic point that is "similar" to the wild type PPV. Therefore, the instant invention is anticipated by Verrelmann et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 4, 6-15 and 19-22 are rejected under 35 U.S.C. 103(a) as being as being obvious over Fernandez-Fernandez et al. (Federation of European Biochemical Societies, 1998) in view of Fitchen et al. (U.S. Pat. No. 5,955,647) and Atreya et al. (Proceeding of the national Academy of Sciences, 1993).

The instant invention is drawn to a recombinant vector expressing a heterologous peptide at the amino terminus of a potyvirus coat protein. The vector comprises enough viral sequence to allow viral replication and spread within the plant. The heterologous sequence can be from a wild type potyvirus. The potyvirus of is a ZYMV. The virus can either be in the form of a DNA sequence and RNA sequence or a cDNA sequence. The coat protein includes an amino terminal domain, wherein the modification is by deletion of at least one amino acid residue. The vector can also have one additional amino acid residue added to the polyprotein. The recombinant vector further comprises an amino acid substitution in the HC-Pro gene. Aphids do not transmit the virus effectively. The recombinant vector comprises a c-Myc tag.

Fernandez-Fernandez et al. teaches the construction of a recombinant potyvirus (plum pox potyvirus vector; PPV) which comprises a heterologous nucleic acid sequence encoding canine parvovirus VP2 capsid protein (CPV). The non-aphid transmissible PPV was used for the cloning of the 15 amino acid sequence of CPV (see material and methods). The mutants created in the reference were able to infect plants and replicate (see page 230, column 2, last paragraph). The PPV amino terminal domain was deleted of at least 45 nt (15 amino acids) that were then replaced by the addition of 45nt from the CPV in order to established the number of amino acids present in the wild type PPV (see page 231, column 1, 1st paragraph). Since the sequence does not contain additional amino acids the sequence would be expected to have an isolelectic point

that is "similar" to the wild type PPV. The chimeric PPV-CPV particles were tested in laboratory animals (rabbit and mouse) to see if they are able to induce neutralizing antibodies (see page 233, table 1 and page 234, table 2). The reference does not teach the use of a c-Myc tag for the production and purification of a plant viral coat protein, or the addition of an amino acid residue to enhance the excision of the coat protein or the attenuation of the potyvirus.

Fitchen et al. (U.S. Pat. No. 5,955,647) teaches the use of c-Myc as an antigen in the tobacco mosaic virus (TMV) coat protein (column 10, lines 27-35, table 1). The reference teaches that the use of a known antigen is beneficial as the antibodies necessary for analysis are readily available. The reference teaches the overproduction of peptides and proteins in a plant using TMV.

Atreya et al. (Proceeding of the national Academy of Sciences, 1993) teaches the effect of amino acid substitutions, deletions and gene replacements on the virulence and aphid transmissibility. The HC-pro region is a domain that is essential for infectivity (see page 11922, column 2, 2nd paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a c-Myc tag in a potyvirus expressing a heterologous coat protein construct for the purpose of either using c-Myc as a purification tag or for the purpose of tracking the expression of the epitope in the plant as suggested by Fitchen et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize an attenuated potyvirus for the purpose of expressing a heterologous protein so that the plant will not succumb to the effect of the virus infection as taught by Atreya et al. One having ordinary skill in the art would have had a high expectation of success in combining the teaching of the production of a

potyvirus having attenuated symptoms with the potyvirus expression vector taught by Fernandez-Fernandez et al. for the production of a virus having a chimeric coat protein. Therefore, the instant invention is obvious over Fernandez-Fernandez et al. in view of Fitchen et al. and Atreya et al.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

The official fax phone number for the organization where this application or proceeding is assigned is 703-872-9306; for informal communications please the fax phone number is 571-273-0912.

ULRIKE WINKLER, PHD.
PATENT EXAMINER
9/16/04